Remarks

I. Status of the claims

Claims 1, 4, 7-12, 23 and 28-33 are pending and stand rejected. Claims 1, 9, 30, 32, and 33 are amended herewith without prejudice. No new matter has been added.

II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4, 7-12, 23, and 28-33 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner states that "[n]owhere in the specification is there are a mention of 1-15% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose." The Examiner further states that "[t]he closest to mentioning a mixture is recited at page 5, lines 3-5, wherein blending about 1-80% of a selected pharmaceutically active agents with about 1-60% of uncrosslinked linear polymer such as hydroxyethyl cellulose and 1-15% of another crosslinked polymer hydroxypropyl methylcellulose." Applicants respectfully traverse this contention.

Firstly, Applicants submit that a closer mentioning of a mixture is recited in claims 1, 2, and 5 as originally filed. Claim 1 was drawn to a controlled release pharmaceutical delivery device comprising in part 1 to 75% by weight uncrosslinked, linear water soluble polymers. Dependent claim 2 further defined the uncrosslinked polymers as cellulose ethers and their derivatives. Dependent claim 5 further defined the cellulose ethers and their derivatives as selected from the group consisting of hydroxyethyl cellulose, hydroxypropyl methyl cellulose, ethylcellulose and hydroxypropyl cellulose. Claim 1 was later amended in a Response and Amendment dated September 10, 2001, to specify that the 1 to 75% by weight uncrosslinked, linear water soluble polymers are a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose.

Secondly, regardless of the support for 1 -75% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose, the Examiner contends that there is no written description for 1-15% by weight presently claimed. Applicants submit

that, contrary to accepted patent law, the Examiner is mistakenly requiring a literal listing of 1-15% by weight in order for the specification to adequately support this limitation. Applicants respectfully note that:

> "The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language."

In re Kaslow, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983).

Moreover, "[b]roadly articulated rules are particularly inappropriate" when applying the written description requirement to narrowed claims involving ranges. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). In *Wertheim*, the invention was directed to a process for making freeze dried instant coffee. The priority application disclosed a solids concentration of the coffee extract of 25 to 60% and provided examples of 36 and 50%. The claims included the limitation of a solids concentration of "between 35 and 60%." The PTO rejected these claims for failing to comply with the written description requirement. The C.C.P.A. held that the PTO failed to establish a prima facie case of non-compliance with the written description requirement, even though the priority application lacked literal support. Specifically, the PTO provided no evidence that that one skilled in the art would not view the narrower range as within Wertheim's invention. *Id.* at 264, 191 U.S.P.Q. at 98.

The present claims are analogous to those of Wertheim in that Applicants have narrowed the claims to a range of 1-15%, which falls within the originally claimed range of 1-75%. Thus, like the Wertheim case, this narrower range is adequately supported by the specification. For at least these reasons, Applicants respectfully request withdrawal of this rejection.

The Examiner also contends that the specification does not support the phrase "the amount of hydroxyethyl cellulose and hydroxypropyl methylcellulose affects the release rate of [the]

selected pharmaceutical[ly] active substance. (*Office Action* at p. 3.) Solely to expedite prosecution, Applicants have deleted this phrase from all of the pending claims. Applicants respectfully request entry of these amendments and withdrawal of the §112, first paragraph rejection.

III. Provisional Non-Statutory Double Patenting

Claims 1, 4, 7-12, 23 and 28-33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent Application No. 11/473,386 ("the '386 application"). Applicants respectfully request that the Examiner hold in abeyance this obviousness-type double patenting rejection until allowable subject matter is indicated, at which point Applicants will file a terminal disclaimer if necessary.

IV. Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Dated: August 27, 2007

Respectfully submitted,

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